

REMARKS

Claims 7-29, 33-34, 43-46, and 48-49 are pending in this application, with claims 27-29, 33-34, 43-46 and 48-49 being under consideration.

Applicants submit that no new matter is presented herein.

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections in view of the remarks presented below.

The Presently-Claimed Invention

The presently-claimed invention relates, generally, to a packaged antimicrobial elastomeric article that is essentially free of powder and starch, and is coated on an outside surface with at least one antimicrobial agent. The package comprises a desiccant for reducing the relative humidity in the vicinity of the elastomeric article to less than the ambient relative humidity. The antimicrobial activity of the elastomeric article is extended compared to an unpackaged elastomeric article.

The claimed elastomeric articles beneficially minimize or reduce cross-contamination that can occur as a result of contact by a wearer or user of the article with more than one other object. When the antimicrobial agent is applied to the surface in contact with the wearer's hand, the elastomeric articles also inhibit growth of skin flora. See paragraph [0034]. The package system, which includes a moisture-resistant water-vapor impermeable barrier and a desiccant, reduces relative humidity and maintains said reduced relative humidity in the vicinity of the antimicrobial elastomeric article. See paragraph [0037]-[0038].

Rejection under 35 U.S.C. § 103(a)

Claims 27-31, 33-34, 43-46, 48-49 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman") and U.S. Patent No. 5,357,636 ("Dresdner").

Applicants respectfully traverse this rejection.

The Office Action relies upon Modak for disclosing an antimicrobial elastomeric article that includes anti-infective agents such as chlorhexidine salts and a lubricating agent. The coating of Modak may further comprise quaternary ammonium halides such as benzalkonium chloride, and biomedically acceptable polymers such as polyurethanes and silicones. The polymers may be used to "minimize the possibility of lubricating agent being released from the glove surface and to provide lubricity due to the nature of the polymeric component." See col. 3, lines 1-4.

The Office Action admits that the anti-infective agent of Modak is not provided on the outside surface of the elastomeric article, but cites Dresdner for disclosing providing a coating on an outside surface of an elastomeric article (citing Example 1). Dresdner is also cited for disclosing sterile packaging of elastomeric gloves, and use of chlorhexidine gluconate and benzalkonium chloride as antiseptic agents.

The Office Action also admits that Modak does not disclose a process for extending antimicrobial activity.

McDevitt is cited for disclosing a finger glove that is contained in a package "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." See paragraph [0189].

Shichman is cited for disclosing adding a dessicant to a package to reduce moisture.

Applicants submit that the combination of Modak, Dresdner, McDevitt, and Schichman fails to disclose or suggest the presently-claimed invention for at least the following reasons.

Modak relates to an antiviral surgical or examination glove including a biguanide anti-infective agent and a lubricating agent/donning aid. See col. 2, lines 20-22. A suitable lubricating agent may include powders such as zinc oxide, hydroxycellulose, or corn starch that has been blocked with benzalkonium chloride, didecyldimethylammonium chloride, or gluconic acid. See col. 2, lines 20-22 and 51-63. When corn starch is used, the corn starch is blocked in order to prevent the anti-infective agent from being adsorbed. The biguanide anti-infective agent is provided inside the glove to protect health care workers from exposure to pathogens, such as HIV and HBV. See col. 1, lines 32-40.

In describing the process for forming gloves, Modak discloses that

After the leaching step, the inner coating was formed by dipping the leached glove into a powder slurry containing 15% cornstarch, 0.2% Bardac 2250 and 2% chlorhexidine gluconate (CHG). To form this slurry 450 g of cornstarch was suspended in water and diluted to 2700 ml deionized water, and 6 ml of Bardac 2250 was added to it and mixed well. This solution was mixed by placing on a magnetic stirrer and 300 ml of 20% CHG was added slowly and the mixing continued for 20 minutes. This slurry was then ready for use.

Finally, the CHG treated glove was dried in an oven at 100°C for 1 hour to complete the gloves, which were then removed from the forms.

See column 5, lines 9-21.

Each embodiment and example described in Modak requires that the glove be coated with a slurry containing a non-adsorbent lubricating agent (i.e., a starch or powder), and an antiviral agent. See Example 1 (slurry containing 15% cornstarch and 2% CHG), Example 2 (slurry containing 15% cornstarch and 2% CHG), Example 3 (slurry containing 5% zinc oxide powder and 1-2% CHG), Example 4 (2% hydroxyethylcellulose, optionally 1% zinc oxide powder, and 1-2% CHG), and Example 7 (8% cornstarch and 2% CHG). Even the comparative examples set forth from col. 5, line 55 to col. 6, line 60 are based on preparing gloves using slurry dip coatings containing starch and CHG. All of the slurries described in Modak contain starch or powder lubricants such as cornstarch, hydroxyethylcellulose, and zinc oxide. There is

no disclosure or suggestion in Modak of gloves having antiviral inner coatings that are essentially free of powder and starch.

In the "Response to Arguments" section, the Office Action takes the position that Applicants have argued that Modak specifically teaches that the lubricating agent is preferably a modified corn starch. This statement evidences a failure to grasp Applicants' above arguments, which are substantially repeated from the Amendment filed on February 1, 2010. Applicants have clearly indicated that Modak discloses gloves in which powder and/or starch are required as a lubricating agent. The presently-claimed invention relates to elastomeric articles that are essentially free of powder and starch. Even in the embodiments of Modak where starch is not used, a powder is used. There are **NO** embodiments of Modak that are essentially free of both powder and starch.

The Office Action also takes the position that Example 4 of Modak discloses a slurry of 2% hydroxyethylcellulose and 1-2% CHG. The Office Action includes a calculation that a slurry containing 2% hydroxyethylcellulose would contain 0.002 mg of hydroxyethylcellulose, and that therefore less than 2 grams of hydroxyethylcellulose would necessarily be deposited on the glove. However, Applicants submit that the math used to arrive at this conclusion is clearly erroneous. Assuming that the slurry is formed in 1 liter of water (as was assumed in the Office Action), then 1 liter of water is equivalent to 1 kg or 1000 mg of water. It is clear that 2% of 1000 mg is 20 mg, not 0.002 mg. More than enough hydroxyethylcellulose would be present in a slurry containing 20 mg of hydroxyethylcellulose to form a coating of at least 2 mg of hydroxyethylcellulose on a glove.

The Office Action admits that Modak does not disclose a glove that has an outer coating of anti-infective agent, and one skilled in the art would not be motivated to make this modification because Modak relates to protecting the hands of the person wearing the glove. With respect to the assertion that Dresdner remedies this deficiency because it discloses a glove having an antimicrobial coating on the outer surface, Applicants respectfully disagree.

Dresdner is directed to medical gloves that include a non-liquid antiseptic composition that is provided **between** inner and outer elastomeric layers of a glove, so that the antiseptic composition can protect the hand of the wearer from infections if the glove is punctured. See Abstract and Figure 2A. Providing an antiseptic composition sandwiched between glove layers is not the same as providing a glove having an outer antiseptic coating, and Applicants submit that one skilled in the art would not modify the glove of Modak, which has an inner antiseptic coating, to provide an outer antiseptic coating thereon based on the disclosure of Dresdner. Like Modak, the primary goal of Dresdner is to protect the hands of the person wearing the glove, not prevention of cross-contamination. Further, Applicants submit that one skilled in the art would recognize that the antiseptic composition of Dresdner that is sandwiched between glove layers would not be suitable for use on the outside surface of an elastomeric article. These distinctions are clear from the description of how to prepare such a glove that is set forth in Example 1.

Example 1 of Dresdner describes a method that includes forming a first, inner polyethylene plastic glove layer on a first glove mold, forming a second, larger, outer neoprene rubber glove layer on a second glove mold, and preparing an antiseptic composition primarily comprising polyethylene glycol and glycerin. The **inner** surface of the outer neoprene rubber glove layer is coated with the antiseptic composition, and is then slipped over the inner polyethylene glove layer (which is still on the mold) so that the antiseptic composition is provided **between** the glove layers. Once the glove has cooled and the antiseptic composition has gelled, the ends of the glove layers are sealed using a silicone-containing glue. Applicants submit that there is not even a transitory period during which the outer surface of an elastomeric article is coated with an antimicrobial agent.

In the "Response to Arguments" section, the Office Action alleges that Dresdner discloses that "the outer surface of the inner layer of the glove (e.g., the outside surface of item (2) of Fig. 1B) meets the instant specification's definition of 'outer surface' since this surface comes into contact with other objects, such as medical instruments (see,

e.g., col. 19, lines 59-67 and Fig 2A and 2B) and does not contact the wearer's skin." The Office Action then indicates that the instant claims do not preclude the extra layer that covers the antiseptic composition. However, Applicants submit that this interpretation of Dresdner and the meaning of the term "outer surface" is improper because it is so broad as to render the term "outer surface" meaningless and effectively remove it from the claim. Although the PTO is permitted to give claim terms their "broadest reasonable interpretation consistent with the specification," this must be consistent with the interpretation that those skilled in the art would reach. See MPEP 2111, citing *In re Cortright*, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999)

This definition of the claim term "outer surface" set forth in the specification is as follows:

"[A] preferred embodiment according to the invention is prepared by applying the antimicrobial coating composition to the outer surface of a medical or industrial glove to minimize or reduce cross-contamination as a result of multiple contacts. By outside surface is meant the portion of the glove that comes into contact with other objects such as patients, medical instruments, table tops, or counters." See page 11.

Applicants submit that one skilled in the art would not interpret an outer coating that may be used to reduce cross-contamination as a result of multiple contacts between patients, instruments, table tops, and counters to encompass the inner coating of Dresdner, which is sandwiched between elastomeric layers, and where the inner coating is released when the elastomeric layers are punctured. The claim construction advanced in the Office Action is erroneous, and one skilled in the art would not look to Dresdner for guidance to prepare an elastomeric article having an antimicrobial coating on an outer surface.

Accordingly, based on the disclosures of Modak and Dresdner, one skilled in the art would not prepare an essentially starch and powder-free elastomeric article that is coated on an outside surface with at least one antimicrobial agent.

These deficiencies are not remedied by McDevitt and/or Shichman.

McDevitt relates to a finger glove formed from a nonwoven web material that is liquid impermeable, but vapor permeable. The finger glove may also include an elastic nonwoven material to provide form-fitting properties. The finger glove of McDevitt is intended for use as an applicator or personal cleaning product, such as a swab or oral hygiene device, but there is no disclosure of a packaged elastomeric article that is essentially free of powder and starch and is coated on an outside surface with at least one antimicrobial agent.

Shichman merely discloses packages containing desiccants for preserving bioabsorbable articles, such as surgical staples and clips, and instruments that contain such articles. The articles do not incorporate antimicrobial agents, and there is no disclosure of preserving antimicrobial activity of an elastomeric article that is essentially free of powder and starch and is coated on an outside surface with at least one antimicrobial agent.

For at least these reasons, Applicants again submit that one skilled in the art would not look to Dresdner, McDevitt, and/or Shichman to remedy the deficiencies of Modak with respect to the presently-claimed invention.

Applicants respectfully submit that the combination of Modak, Dresdner, McDevitt, and Shichman fails to disclose or suggest a packaged antimicrobial elastomeric article that is essentially free of powder and starch, is coated on an outside surface with at least one antimicrobial agent, and is provided in a package comprising a desiccant for reducing relative humidity in the vicinity of the elastomeric article, in order to extend the antimicrobial activity of the elastomeric article.

Nothing in the disclosures of Modak, McDevitt, and Shichman would lead one skilled in the art to modify them to arrive at the presently-claimed invention without the benefit of hindsight reconstruction based on Applicants' disclosure. Applicants therefore submit that claims 27-29, 33-34, 43-46 and 48-49 are not unpatentable over the combination of Modak, McDevitt, and Shichman, and respectfully request withdrawal of this rejection.

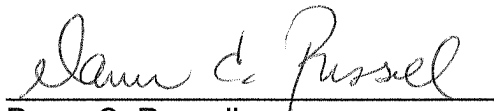
CONCLUSION

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 27-29, 33-34, 43-46 and 48-49, and the prompt issuance of a Notice of Allowance are respectfully requested.

Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing docket number **029714.00017**.

Respectfully submitted,



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